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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/580,541

05/26/2006

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CHANG220

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EXAMINER

SAKELARIS, SALLY A

ART UNIT

PAPER NUMBER

1797

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/580,541	<b>Applicant(s)</b> CHANG ET AL.	
	<b>Examiner</b> Sally A. Sakelaris	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 1-12 and 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendment***

The amendment filed 8/20/2009 has been received and considered for examination.

Claims 13-34 remain pending.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 13-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding (US Patent 5,635,358) in view of McNeely et al (US Patent 6,296,020).

With regard to claim 13, Wilding et al teach: A blood injecting chamber (Figure 7, 16A-D); plural micro-channels one end of which is connected to the blood injection chamber (Figure 7, 20A-C, etc); plural reagent storage chambers connected to the other end of the micro-channel (Figure 7, 22A-D); plural micro-filters connected with reagent storage chambers respectively (Fig. 8-10, (24)); and plural reading channels connected to the micro-filters respectively (Fig. 7, 40); wherein the micro-filters have plural filter poles (26), and the plural filter poles are arranged so as not to pass an agglutinated blood mixture (Figure 5, (26)).

With regard to claims 14-18, and 28 and 29 Wilding teach plural reading parts arranged in parallel (40), the filter chamber (22B or 28) with plural filter poles (26 or filter elements in 28) formed in the filter chamber, the width of the filter pole is longer than its length in a cross sectional view (Fig. 7, 28) and the filter poles are allocated crossly to the direction of the fluid

Art Unit: 1797

which passes through the microfilter (22B or 28), and a first blood resistance part (22B with 24) is formed between the storage chamber and the micro-filter.

With regard to claims 22-24 and 32-34 an inhaling hole is taught in any of (16A-D) at the end of the reading channel (40). Claims 23, 24 and 34 recite intended uses for the aforementioned device components above and will not be afforded patentable weight.

With regard to claim 25 and 26, a base plate is taught in Col. 3 line 41 wherein: "The chips typically will be used with an appliance which contains a nesting site for holding the chip". a chip plate (14), reading chambers (within 40) located on the reading channel (40) and form a transparent reading window(12).

With regard to claim 27, the chip plate is taught to be made from Teflon (Col. 5 line 54).

Generally, Wilding et al teach in their Table 1 that their invention has "no limits to the number of chip designs or applications available" (col.4) and in Figures 1 and 7 provide only examples of how their chips may be arranged. The plural reading channels for example, can be placed in varied locations on the chip as necessitated by the process at hand. Wilding et al. teach the placement of these plural reading channels to occur either upstream or downstream of the micro-filters (Fig. 1 and 7).

With regard to claims 13-34, particularly the new recitations in claim 13 and those of claims 19-21 and 30-31, Wilding et al. do not teach a first blood resistant or hydrophobic surface-processed part which is hydrophobic on the bottom of the first resistance channel which is capable of holding the blood in the reagent storage chambers, nor do they teach a second blood resistance part comprising a second hydrophobic surface processed part which is hydrophobic on the bottom of the reading channel and finally Wilding does not teach the particular embodiment

Art Unit: 1797

applicant has envisioned in a single example in their specification or in figures 1 or 7, instead they teach different elements within different embodiments of their disclosure.

McNeely et al teach the blood resistant or hydrophobic part in their teaching of control of fluid flow through microchannels by use of stopping means in the microchannels (Fig. 2E -J). Fig. 2E illustrates the geometry and position of the stopped fluid if stopping means “a” were that of a hydrophobic restriction. (Col. 7 lines 32-37). Fig 2I illustrates the geometry and position of the stopped fluid if stopping means “a” were that of a hydrophobic patch (Col 7 line 44).

It would have been obvious to insert McNeely’s hydrophobic patches to the bottom’s of resistance channel and to the reading channels of Wilding et al for the because "well planned use of stopping means acting as passive valves allows the flow of fluids through micro-channels to be regulated so as to allow fluids to be mixed or diluted after being introduced via a single channel" (Abstract).

Furthermore, with regard to claims 13-34, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the various features taught by Wilding in view of McNeely et al. in the particular combination claimed by the applicant as Wilding teaches all of the features applicant is claiming and furthermore provides the motivation to vary these features as needed in his teaching that there are “no limits to the number of chip designs or applications available”. Also this flexibility in Wilding et al’s system is attractive as it allows for competitive pricing with existing systems and “expands the capabilities for assay and process monitoring to virtually any system, allowing for a broad range of applications”(Col. 4, Table 1).

***Response to Arguments***

Applicant's arguments filed 8/20/2009 have been fully considered but they are not persuasive.

Applicant first argue that: *Wilding does not disclose the first blood resistance part as now recited in claims 13 and 25. While the examiner has asserted that the first blood resistance part corresponds to Wilding's membrane piercing protrusions 24 in chamber 22B, it is respectfully pointed out to the examiner that Wilding's membrane protrusions 24 tear open the cells (thereby releasing intracellular material from the cells) and does not temporally hold the cells in chambers like a first blood resistance part as recited in the present claims.*

In response, the examiner respectfully points out that the applicant is arguing an intended use for their blood resistance part. It should be noted that as can be seen above the valve of McNeely is capable of performing this holding function used in addition to Wilding's filter poles (26). Applicant is reminded that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Next applicant argues: *Wilding does not disclose or teach that the plural filter poles of the micro-filters are arranged so as not to pass an agglutinated blood mixture. Accordingly, there is nothing in Wilding that would lead one of ordinary skill in the art to arrive at the presently claimed apparatus.*

In response, the examiner respectfully asserts that the applicant has recited an intended use in their limitation "so as not to pass an agglutinated blood mixture". As stated above in the

Art Unit: 1797

rejection, the filter poles (26) of Wilding are capable of blocking an agglutinated blood mixture. It is suggested that applicant add additional structural limitations to their claims so that they may overcome the presently applied art rejections.

In addition, it should be noted that in their newly amended claim 13, the following limitations are being interpreted as an intended use. “temporally holding the blood in the reagent storage chambers during a time in which the blood can be agglutinated with a reagent” and “the plural filter poles are arranged so as not to pass an agglutinated blood mixture”.

Lastly with regard to the rejection over claims 19-21 and 30 and 31, applicant argues:

*The deficiencies of Wilding are discussed above. The secondary McNeely reference is being applied for teaching a stopping means in the micro channels (Figs. 2E-J), but the stopping means merely regulates the flow of fluid through the channels and does not hold the flow of fluid in some chamber. Accordingly, McNeely does not satisfy the deficiencies of Wilding, as discussed above in the preceding obviousness rejection, and therefore cannot lead one of ordinary skill in the art to the presently claimed apparatus.*

As stated above, the examiner maintains that McNeely et al. teaches a passive valving system capable of stopping flow via a “stopping means”(See McNeely col. 5 lines 50-67) not just regulating it as applicant asserts above. The combination of the Wilding and McNeely references makes obvious this newly added limitation to claim 13 as can be seen above.

### ***Conclusion***

Applicant's amendment to claims 13, 20, 25, 30, and 31 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See

Art Unit: 1797

MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sally A. Sakelaris whose telephone number is 5712726297. The examiner can normally be reached on Monday-Friday 8-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 5712721267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. A. S./  
Examiner, Art Unit 1797

/Jill Warden/  
Supervisory Patent Examiner, Art Unit 1797